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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,610	02/12/2001	Jonathan Stanley Harold Denyer	102199-100	3883

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EXAMINER
MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
3761	10

DATE MAILED: 05/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/781,610	DENYER ET AL.	
	Examiner	Art Unit	
	Michael G. Mendoza	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 December 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-38 have been considered but are moot in view of the new ground(s) of rejection.

Drawings

2. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the plurality of vials must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Objections

3. Claim 5 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 1 recites an electronic data carrier in line 4. Claim 5 recites the data carrier is an electronic data carrier.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-8, 13, 14, 18, 20, and 21 are rejected under 35 U.S.C. 102(e) as being anticipated by Hess et al. 6196219.

6. Hess et al. teaches a drug package comprising: a plurality of drug vials 28 containing drugs; an electronic data carrier including drug treatment information 29; wherein the data carrier is arranged to include at least one of the following items of treatment information:

a. the dose of drug to be delivered;

b. the identity of the drug which is to be delivered;

c. the expiry date of the drug to be delivered; and

d. the number of treatments available from the drug package (col. 6, lines 44-48); wherein the drug vials contain drugs adapted for delivery in air inhaled by a patient to their lungs; wherein the drug vials are arranged to be used in conjunction with a drug delivery device for delivering the drug in the inhaled airstream of a patient; wherein the data carrier is arranged to transfer treatment information to a drug delivery apparatus when it is moved to a receptive surface or region of the drug delivery apparatus; wherein the data carrier is arranged to supply drug treatment information to a drug delivery apparatus a number of times corresponding to the number of treatments available from the drug package, or to the number of vials included in the drug package (col. 6, lines 44-48); wherein a single data carrier 29 is included which includes the drug

treatment information for each drug vial; a delivery portion for delivering a drug to a patient; an input for receiving treatment information for each treatment to be delivered to a patient; and a delivery controller for controlling the amount of drug delivered to a patient on the basis of the received treatment information (col. 11, lines 59-65); wherein the input is an electronic input which received the treatment information from an electronic data carrier; wherein the drug delivery apparatus is one of a pneumatic nebulizer, a piezo-electric nebulizer 10, and an ultrasonic nebulizer; wherein the electronic data carrier for holding treatment information concerning the use of the drug delivery apparatus in delivering a specified drug, and an output for transmitting treatment information to the drug delivery apparatus (col. 7, lines 38-46); and an electronic data carrier containing treatment information relating to a specified drug, the treatment information including information relating to the amount of the specified drug to be delivered to a person by the drug delivery apparatus, and the data carrier including an output for transmitting treatment information to the drug delivery apparatus before each treatment with the specified drug, whereby the drug delivery apparatus delivers the specified drug in conformity with the treatment information (col. 11, 59-65).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 9-11 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al. in view of Rode et al. 6315719.

9. As to claim 9, Hess et al. teaches a drug package according to claim 1. It should be noted that Wolf et al. fails to teach wherein the data carrier is a radio frequency device. However, Rode et al. teaches wherein a data carrier is a radio frequency device (col. 3, lines 45-58). Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Hess et al. to include the radio frequency device of Rode et al. to transmit information to a data logger or to a main system.

10. As to claim 10, Hess/Rode teaches a drug package according to claim 9, wherein the data carrier is arranged to be powered from a magnet field associated with the drug delivery apparatus. It should be noted that Hess/Rode fails to specifically teach the particulars of the means for powering the data carrier as set forth by the above claim. However, the particulars of the means for powering are mechanical expedients of each other.

11. Hess/Rode teaches wherein the data carrier is arranged to generate a radio-frequency signal bearing the treatment information; and wherein the input is a radio frequency input which received the treatment information from a data carrier at radio frequency.

12. Claims 12, 16, and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al. in view of Poley et al. 6418924.

13. Hess et al. teaches the drug package according to claim 1. It should be noted that Hess et al. fails to teach wherein the data carrier includes a memory for recording

information concerning treatments received from the drug delivery device. However Poley et al. does teach a memory for recording information concerning treatments received from the drug delivery device. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Hess et al. to include the memory of Poley et al. for determining drug regime compliance (col. 2, lines 49-65).

14. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hess et al in view of Wolf et al. 5505195.

15. Hess et al. teaches the drug delivery apparatus according to claim 13. It should be noted that Hess et al. fails to teach wherein the drug delivery apparatus includes an authorization portion which prevents delivery if any of the treatment information indicates that the drug is unsuitable for delivery. However Wolf et al. teaches wherein the drug delivery apparatus includes an authorization portion which prevents delivery if any of the treatment information indicates that the drug is unsuitable for delivery. Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Hess et al. to include the authorization portion of Wolf et al. to insure proper activation (col. 11, lines 24-34).

16. Claims 22-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wolf et al. in view of Eigler et al. 6,328,699.

17. As to claim 22, Wolf et al. teaches a drug deliver device comprising:

a delivery portion for delivering a drug to a patient 140;

a drug use analyzer which records the use of the drug over a number of treatments as recorded treatment information, which analyses to amount of a drug delivered over a number of treatments and which identifies when only a certain proportion of the prescribed drug remains (col. 13, line 52-67).

It should noted that Wolf et al. fails to teach a repeat prescription ordering portion which operates to submit the recorded treatment information to a data center once the drug use analyzer identifies that less than the certain proportion of the prescribed drug remains, the data center analyzing the recorded treatment information according to a protocol in order to formulate a result that identifies whether certain specifications are satisfied and, where the result indicates that the certain specifications have not been satisfied, referring the patient to a doctor, the doctor treating the patient. However, Eigler et al. does teach a repeat prescription ordering portion (col. 10, lines 60-65) which operates to submit the recorded treatment information to a data center once the drug use analyzer identifies that less than the certain proportion of the prescribed drug remains, the data center analyzing the recorded treatment information according to a protocol in order to formulate a result that identifies whether certain specifications are satisfied and, where the result indicates that the certain specifications have not been satisfied, referring the patient to a doctor, the doctor treating the patient (col. 10, lines 8-45). Therefore it would have been obvious to one of ordinary skill in the art to modify the device of Wolf et al. to include the repeat prescription ordering portion of Eigler et al. to ensure that the user has a new supply of the drug before the drug in the device is exhausted and to insure the proper amount of drug is being used.

18. Wolf/Eigler teaches wherein the repeat prescribed ordering portion includes a modem which automatically connects to a telephone system to electronically order a repeat prescription (col. 13-26); wherein the repeat prescription ordering portion includes a connection to an electronic network through which the repeat prescription is ordered (col. 10, lines 60-65); wherein the drug use analyzer includes a counter for counting the number of drug treatments delivered (col. 13, lines 52-67); wherein the drug analyzer includes a memory for holding the total number of drug treatments that are possible from an existing course of drug treatments (col. 13, lines 52-67); wherein the drug use analyzer includes a comparitor which compared the number of drug treatments that are possible from the memory with the number of drug treatments delivered from the counter, and generates a repeat prescription order signal when only a certain proportion of the prescribed drug remains (col. 13, lines 52-67); wherein the repeat prescription re-ordering portion orders a repeat prescription once it received a repeat prescription order signal from the drug use analyzer (col. 10, lines 60-65); wherein the drug use analyzer includes a data carrier, including drug treatment information including the total number of drug treatments that are possible from an existing course of drug treatments (col. 13, line 52-67); wherein the memory for holding the total number of drug treatments is located in the data carrier (col. 13, lines 52-55).

19. As to claim 31, Wolf/Eigler teaches a method of prescribing a drug, comprising:

supplying a patient with a course of a number of drug treatments 623 for administering using a drug delivery device;

recording the use of the drug treatments (col. 13, lines 35-39);

analyzing the use of drug treatments;

identifying when only a certain proportion of the drug treatments remains (col. 13, line 52-67); and

submitting the recorded treatment information to a data center once only the certain proportion of the drug treatments are identified as remaining (col. 10, lines 60-65); analyzing the recorded treatment information of the data center according to a protocol in order to formulate a result which identifies whether certain specifications are satisfied, and where the result indicates that certain specification have not been satisfied, referring the patient to a doctor (col. 10, lines 8-45); issuing a course of drug treatments or a prescription for the course of treatments in response to the electronic order (col. 10, lines 60-65); wherein the electronic ordering is done via a modem connection to a telephone line (col. 13, line 23-26); wherein the electronic ordering is done via a connection to an electronic network (col. 10, lines 60-65); wherein the analyzing of the use of the drug treatments includes counting the number of drug treatments delivered (col. 13, lines 52-67); wherein the analyzing includes the comparing of the number of drug treatments delivered with the total number of treatments supplied (col. 13, lines 52-67); further including the step of generating a repeat prescription order signal when it is identified that only a certain proportion of the drug treatments remain (col. 10, lines 60-65); and further comprising the supply of a data carrier with the course of a number of drug treatments, the data carrier bearing drug treatment information including the total number of drug treatments that are possible from the existing course of drug treatments (col. 13, lines 52-67).

Conclusion

20. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Mendoza whose telephone number is (703) 305-3285. The examiner can normally be reached on Mon.-Fri. 8:00 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 306-4520 for regular communications and (703) 306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

MM
May 14, 2003

WEILUN LO
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